

WHEREAS Mylan seeks discovery concerning Novartis's Investigational New Drug Application ("IND") No. 58,544 and New Drug Application ("NDA") No. 21-882, nonpublic, confidential documents, which federal law forbids the FDA from disclosing to the public, and other nonpublic, confidential documents in the possession, custody or control of Novartis;

WHEREAS the parties, through counsel, have stipulated to the entry of this protective order for the purpose of advancing the progress of this action and to prevent unnecessary dissemination or disclosure of their respective confidential information; and

WHEREAS the parties, through counsel, stipulate that good cause exists for the entry of this protective order pursuant to Rule 26(c) to safeguard against improper disclosure or use of confidential information produced in this action;

It is hereby ORDERED that the following provisions shall govern the conduct of further proceedings in this action:

Definitions

1. The term "Protected Information" shall include all information that the designating party believes constitutes, discloses or relates to proprietary business information, processes, operations, research, technical or developmental information, production, marketing, sales, shipments or other proprietary data or information of commercial value, including, but not limited to, trade secrets. The information contained therein and all copies, abstracts, excerpts, analyses or other writings that contain, reflect, reveal, suggest or otherwise disclose such Protected Information shall also be deemed Protected Information. Each party shall act in good faith in designating information as Protected Information.

2. The term "Qualified Person" shall mean:

(a) Court and any Court personnel involved with this action;

- (b) Novartis's outside counsel, their legal assistants, and members of their support staffs;
- (c) Mylan's outside counsel, their legal assistants, and members of their support staffs;
- (d) any independent expert or consultant who is retained by counsel solely for the purpose of assisting in this action, subject to the provisions of Paragraph 13;
- (e) photocopy services;
- (f) professional translators who are retained by the attorneys for the parties for the purposes of this litigation;
- (g) stenographic reporters, official court reporters, and their assistants who are engaged in such proceedings as are necessary for the preparation and trial of this action;
- (h) jury or trial consultants and persons employed or retained by them solely in providing litigation support services to the parties' outside counsel law firms;
- (i) document imaging and database services and consultants retained to set up, maintain, and/or operate litigation databases for this litigation;
- (j) graphics or design consultants retained to prepare demonstrative or other exhibits for use in this action;
- (k) up to three in-house personnel for the receiving party who: (i) is responsible for monitoring and/or supervising this action, and (ii) does not engage formally or informally, or directly or indirectly, in any patent prosecution directed to any deferasirox drug product, any method of manufacture of any deferasirox drug product, or any method of treatment or use of any deferasirox drug product for the duration of the litigation and for two years after entry of final judgment from which no appeal may be taken;

- (i) When Novartis is the receiving party, up to three (3) in-house legal personnel employed by Novartis, and their respective secretarial, clerical, paralegal and other supporting personnel. These in-house legal personnel shall include Peter Waibel. Novartis reserves the right to designate two additional in-house legal personnel employed by Novartis at a later date. Before a designated in-house legal person for Novartis may receive CONFIDENTIAL INFORMATION, Novartis must serve (by email) upon counsel of record for all producing parties a completed and signed undertaking in the form of Exhibit A attached hereto from such in-house legal person, but a *curriculum vitae* is not required;
- (ii) When Mylan is the receiving party, up to three (3) in-house legal personnel employed by Mylan, and their respective secretarial, clerical, paralegal and other supporting personnel. These in-house legal personnel shall include Jaime B. Lebo, Jill M. Ondos, and Tom W. Jenkins. Before a designated in-house legal person for Mylan may receive CONFIDENTIAL INFORMATION, Mylan must serve (by email) upon counsel of record for all producing parties a completed and signed undertaking in the form of Exhibit A attached hereto from such in-house legal person, but a *curriculum vitae* is not required.

(l) any other person who is designated as a Qualified Person by order of the Court or by written agreement of the parties.

Use of Protected Information

3. Protected Information will be used solely for the purpose of prosecuting or defending this action.

4. Nothing in this protective order shall prevent any person, including a Qualified Person, from making use of any information that is designated as Protected Information if such information:

- (a) was lawfully in his or her possession prior to receipt under the provisions of this protective order;
- (b) was or becomes available to the public through no fault of a receiving party;

(c) was or is obtained from a source not under an obligation of secrecy to the designating party; or

(d) is exempted from the operation of this protective order by written consent of the designating party.

5. If any person disputes or challenges the designation of any information as Protected Information based on any ground specified in subparagraphs (a) through (c) of paragraph 4, such information shall nevertheless be treated as Protected Information in accordance with the provisions of this protective order until such designation is removed by order of the Court or by written consent of the designating party.

Disclosure of Protected Information

6. Protected Information shall not be made available to anyone other than a Qualified Person or the party who produced such Protected Information, except as otherwise provided in this protective order.

7. Protected Information produced or disclosed by a Defendant shall not be disclosed or produced to any other Defendant, except that such information may, to the extent necessary, be disclosed to outside counsel of record for the other Defendants.

8. A document that contains or reveals Protected Information may be shown to any person who authored or previously had access to or knowledge of the document, as demonstrated by the document itself or by foundation testimony during a deposition, hearing or trial.

9. Protected Information may be disclosed to a witness testifying under oath if the witness is an officer, director, or employee of the party who produced such Protected Information.

10. Protected Information may be disclosed to a witness testifying under oath if (a) the witness was formerly an officer, director, or employee of the party who produced such Protected Information; (b) the Protected Information was in existence during the period of his or her service or employment; and (c) a foundation is established that the witness was involved in the project to which the Protected Information relates.

11. This order shall not prevent counsel from examining a witness testifying under oath in a good-faith effort to determine whether the witness has discoverable information about the Protected Information.

12. Nothing in this protective order shall prevent disclosure of Protected Information if the designating party consents to such disclosure or if the Court, after notice to all parties, orders such disclosure.

13. Counsel desiring to disclose Protected Information to an individual according to paragraph 2(d), 2(f), 2(h), 2(j), 2(k), or any other person according to paragraph 2(l) shall first obtain a signed declaration in the form shown in attached Exhibit A from that person. For independent experts or consultants according to paragraph 2(d), or for any changes to the individuals identified in subparagraph 2(k), at least ten (10) days in advance of the proposed disclosure of any Protected Information to that person, counsel shall serve that person's signed declaration and curriculum vitae or resume by facsimile or electronic mail on every other party. The identification of an independent expert or consultant according to paragraph 2(d) shall include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-date curriculum vitae, any prior or current employments or consultancies for any party within the last five years (except those engagements that are protected from disclosure pursuant to Fed. R. Civ. P. 26), including a list of the cases in which the expert or consultant has

testified at deposition, at a hearing, or at trial within the last four years. A party may object for cause to the proposed disclosure by serving a written objection on every other party within ten (10) days after receiving the copy of the signed declaration. Failure to timely object shall operate as a waiver of the objection. If a party objects to the proposed disclosure, the objecting party's Protected Information shall not be disclosed to such person except by order of the Court or by written consent of the objecting party. In the event that a motion is made, the objecting party shall have the burden of proving that disclosure should not be made.

14. Anyone according to paragraph 2 who receives Protected Information shall not be involved, on behalf of any party, in the preparation or prosecution of any patent application directed to EXJADE[®] described in NDA No. 21-882, the accused products described in ANDA No. 206585, or any deferasirox drug product, any method of manufacture of any deferasirox drug product, or any method of treatment or use of any deferasirox drug product for the duration of this action and for two years after entry of final judgment from which no appeal may be taken.

15. If a party intends to reveal Protected Information of another party during a trial, court appearance, or hearing, which is open to the public, the party intending to reveal such Protected Information shall provide reasonable notice and opportunity to object to the party that produced the Protected Information, unless consent from the party that produced the Protected Information party was previously obtained.

Identification and Marking of Protected Information

16. Any document or other tangible thing that contains or reveals Protected Information shall be labeled with the legend "CONFIDENTIAL INFORMATION UNDER PROTECTIVE ORDER" or a marking of like import. Such marking shall appear on each page of the document that contains Protected Information. For pleadings and discovery responses,

such marking need only appear on the first page of the document. Any document or other tangible thing so labeled and the information that it contains or reveals shall be treated in accordance with the provisions of this protective order. Any Protected Information not reduced to documentary or physical form or which cannot be conveniently labeled shall be so designated by a party by serving a written notification on the receiving party within a reasonable amount of time after disclosure.

17. When a party initially produces documents for inspection, no marking need be made by the producing party in advance of the inspection. For purposes of the inspection, all documents shall be treated as containing Protected Information. After the receiving party selects specified documents for copying, the producing party shall appropriately mark the copies of the selected documents before they are provided to the receiving party.

18. Only Qualified Persons, subject to the limits set forth in paragraph 7, the deponent, and the court reporter shall be allowed to attend any portion of a deposition in which Protected Information is used or elicited from the deponent.

19. All deposition transcripts shall be deemed to be and shall be treated as containing Protected Information. To de-designate deposition testimony, the requesting party must first provide written notice to all counsel of record of the specific pages and lines that do not contain Protected Information. No deposition testimony shall be de-designated without consent by all parties or Court order.

20. A non-party to the litigation (e.g., a third party producing information pursuant to subpoena) may designate such information as Protected Information as set forth in Paragraph 16, *supra*. If so designated, such Protected Information shall be subject to the same restrictions and conditions as information designated by any party as Protected Information.

Inadvertent Failure to Designate

21. The inadvertent failure by a producing party to designate specific documents or materials as containing Protected Information shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or materials. Upon notice to the receiving party of such failure to designate, the receiving party shall cooperate to restore the confidentiality of the inadvertently undesignated information. No showing of error, inadvertence, or excusable neglect shall be required for redesignation.

Inadvertent Production of Privileged or Protected Documents

22. The inadvertent production of documents or materials subject to the attorney-client privilege, work-product immunity, or other protection mandated by local law shall not constitute a waiver of such privilege, immunity, or other protection. After receiving notice from the producing party that documents or materials subject to the attorney-client privilege, work-product immunity, or other protection have been inadvertently produced, the receiving party shall not review, copy, or otherwise disseminate the documents or materials, nor shall it disclose their substance. In addition, the receiving party shall return the documents or materials and all copies within five (5) days from receiving notice, or provide written confirmation of the destruction of the original and all copies of the identified document. The receiving party shall not utilize the information contained in the inadvertently produced documents or materials for any purpose, or disseminate or transmit such information.

(a) If the receiving party wishes to contest that any such document or thing is protected by the attorney-client privilege, work-product immunity, or other protection mandated by local law, the receiving party shall so notify the producing party in writing when the document or thing is returned to the producing party (“Notice of Designation”).

(b) Within five (5) days after receiving a Notice of Designation, the producing party shall provide to the receiving party for each such document or thing a description of the basis for the claim of privilege, immunity, or other protection.

(c) Within five (5) days after receiving such description, the receiving party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed. In any such motion to compel production of the inadvertently produced document, the receiving party shall not rely upon in any manner or assert as a ground for ordering production the fact, circumstances, or contents of the inadvertent production.

(d) With respect to documents and things generated by a receiving party, which documents and things contain information derived from such inadvertently produced documents and things, if the receiving party does not notify the producing party that the receiving party disputes the claim of attorney-client privilege, work-product immunity, or other protection, or if the Court rejects any challenge by the receiving party to the privileged status of the inadvertent production, the receiving party shall either destroy the derivative documents and things or redact from them all such derivative privilege or work-product information in a manner such that derivative information cannot in any way be retrieved or reproduced.

Challenges to Protected Information Designation

23. A party shall not be obligated to challenge the propriety of a Protected Information designation at the time made, and a failure to do so shall not preclude a subsequent challenge thereto. In the event that a party disagrees at any time with a Protected Information designation made by another party, the parties shall make a good-faith attempt to resolve the dispute on an informal basis. If the parties cannot resolve the dispute, the objecting party may

seek appropriate relief from the Court, and the designating party shall have the burden of proving that its Protected Information designation is proper.

Filing of Protected Information

24. The Clerk of the Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court that has been designated, in whole or in part, as containing or revealing Protected Information.

25. In the event that a party wishes to use any Protected Information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court, such paper shall be enclosed in a sealed envelope or other appropriate container. The sealed envelope or other appropriate container shall:

- (a) show the caption of this action;
- (b) identify its contents; and
- (c) include the following legend:

**CONFIDENTIAL INFORMATION
SUBJECT TO PROTECTIVE ORDER**

This envelope [or container] is sealed pursuant to court order and contains confidential and proprietary information. This envelope [or container] was filed by [name of party] and may not be opened, nor may its contents be displayed or revealed, except by court order or by written stipulation of the parties.

Advice to Clients

26. Nothing in this protective order shall bar or otherwise restrict an attorney herein from rendering advice to his or her client with respect to this action and, in the course thereof, referring to or relying upon his or her examination of Protected Information. In rendering such advice and in otherwise communicating with his or her client, the attorney shall not disclose any

Protected Information if such disclosure would be contrary to the provisions of this protective order.

Discoverability of Expert Materials

27. Discovery of communications between counsel and any independent expert or consultant retained or specially employed by that counsel shall be limited to factual information, analyses, documents, and data considered or relied on by the expert in rendering the opinions expressed in an expert report or at trial. Except as otherwise provided herein, all other communications between counsel and the expert relating to the process of preparing an expert report or developing opinions for trial, including all preliminary or draft reports, expert working papers, notes, and communications relating thereto, shall be deemed exempt from discovery and use at trial.

Third-Party Requests

28. If any third party requests the production of any Protected Information, including but not limited to a request by subpoena, the receiving party in possession of such Protected Information must:

- (a) notify the producing party within 7 days of receiving the request; and
- (b) take all lawful steps necessary to assert (or permit the Producing Party to assert) all applicable protections, including but not limited to:
 - (i) permitting the producing party a reasonable opportunity to intervene and be heard, and
 - (ii) defending the asserted rights, privileges, and immunities if the producing party cannot be heard.

Other Proceedings

29. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant

and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "confidential" pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

Miscellaneous

30. No party shall be responsible to another party for any use made of information that was produced and not designated as Protected Information.

31. Should any Protected Information be disclosed, through inadvertence or otherwise, by a receiving party to any person not duly authorized to receive such information under this Protective Order, then the receiving party responsible for such disclosure shall promptly notify opposing counsel of all pertinent facts and make every effort to prevent further unauthorized disclosure, including retrieving all copies of the Protected Information from the unauthorized recipient(s) thereof and requesting that each such recipient execute the declaration attached as Exhibit A.

32. Documents and things produced or made available for inspection may be subject to redaction, in good faith by the Producing Party, of information that is neither relevant to the subject of these Actions nor reasonably calculated to lead to the discovery of admissible evidence, or is subject to the attorney-client privilege or work product immunity. Any such redaction shall be clearly labeled. All documents redacted based on attorney-client privilege or work product immunity shall be listed in a privilege log stating the basis for such redaction.

33. Nothing in this protective order shall prejudice the right of any party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

34. Nothing in this protective order shall prejudice the right of any party to seek at any time a further order modifying this protective order.

35. Nothing in this protective order shall prejudice the right of any party to bring before the Court at any time the question of whether any greater or lesser restrictions should be placed upon the disclosure of any Protected Information.

36. In the event that a new party is added, substituted, or brought in, this protective order will be binding on and inure to the benefit of the new party, along with the corresponding obligations on the new party to maintain the confidentiality of the Protected Information, subject to the right of the new party to seek relief from or modification of this protective order.

37. Nonparties who produce information in this action may avail themselves of the provisions of this protective order.

38. Within ninety (90) days after the termination of this action (including any appeals), each document and each other tangible thing that contains or reveals Protected Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information shall be either (a) returned to the attorney of record for the producing party or (b) destroyed with a representation of such destruction being made to the attorney of record for the producing party. Notwithstanding the foregoing, outside counsel for a receiving party may retain one complete set of each parties' document production and any other Protected Information contained in outside counsel's work product, correspondence between outside counsel, depositions or in copies of pleadings and materials filed with the Court.

39. Within ninety (90) days after the termination of this action (including any appeals), any Protected Information that was filed under seal with the Clerk of the Court shall be returned to the attorney of record for the filing party.

40. The provisions of this protective order shall survive and remain in full force and effect after the termination of this action (including any appeals).

41. This protective order may be amended as need may arise by written agreement of the parties, subject to court approval.

The foregoing protective order is agreed to and accepted as to both form and substance.

**SCHRADER BYRD & COMPANION,
PLLC**

/s/ James F. Companion
James F. Companion (#790)
The Maxwell Centre
32 – 20th Street, Ste. 500
Wheeling, WV 26003
Telephone: (304) 233-3390
Facsimile: (304) 233-2769
jfc@schraderlaw.com

*Attorneys for Plaintiffs
Novartis Pharmaceuticals Corporation
and Novartis AG*

OF COUNSEL:

Jane M. Love
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800
jane.love@wilmerhale.com

Lisa J. Pirozzolo
Kevin S. Prussia
Shirley X. Li Cantin
WILMER CUTLER PICKERING
HALE AND DOOR LLP
60 State Street
Boston, MA 02109
(617) 526-6000
lisa.pirozzolo@wilmerhale.com
kevin.prussia@wilmerhale.com
shirley.cantin@wilmerhale.com

Dated: March 4, 2015

STEPTOE & JOHNSON PLLC

/s/ Gordon H. Copland
Gordon H. Copland
(W. Va. State Bar I.D.: 828)
gordon.copland@steptoe-johnson.com
400 White Oaks Blvd.
Bridgeport, WV 26330
Phone: (304) 933-8162
Facsimile: (304) 933-8183
Gordon.Copland@Steptoe-Johnson.com

*Attorneys for Defendants
Mylan Pharmaceuticals Inc.
and Mylan Inc.*

OF COUNSEL:

Nicole Stafford
Eric Arnell
WILSON SONSINI GOODRICH &
ROSATI
900 South Capital of Texas Highway,
Las Cimas IV, Fifth Floor
Austin, TX 78746
Tel: (512) 338-5400
nstafford@wsgr.com
earnell@wsgr.com

Sami Sedghani
WILSON SONSINI GOODRICH &
ROSATI
One Market Plaza
Spear Tower, Suite 3300
San Francisco, CA 94105
Phone: (415) 947-2000
Facsimile: (415) 947-2099
ssedghani@wsgr.com

7. I will hold in confidence, will not disclose to anyone not qualified under the Stipulated Protective Order, and will use only for purposes of this action, any Protected Information that is supplied to me.

8. I will return each document and each other tangible thing that discloses or reveals any Protected Information to the attorney who provided such document or other tangible thing to me. Moreover, I will deliver any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information to the attorney who provided such Protected Information to me.

9. I understand that if I violate the provisions of the Stipulated Protective Order, I will be in violation of a Court order and subject to sanctions or other remedies that may be imposed by the Court and potentially liable in a civil action for damages.

10. I hereby submit to the jurisdiction of the United States District Court for the District of Delaware for the purpose of enforcement of the Stipulated Protective Order.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

Dated: _____